



Harnessing the Web to Streamline Statistical Programming Processes

TT03

Daniel Boisvert

Purpose

- Share high level overview and key features of our applications
- Encourage web development for other Biometrics applications

Biogen Biometrics Web Applications

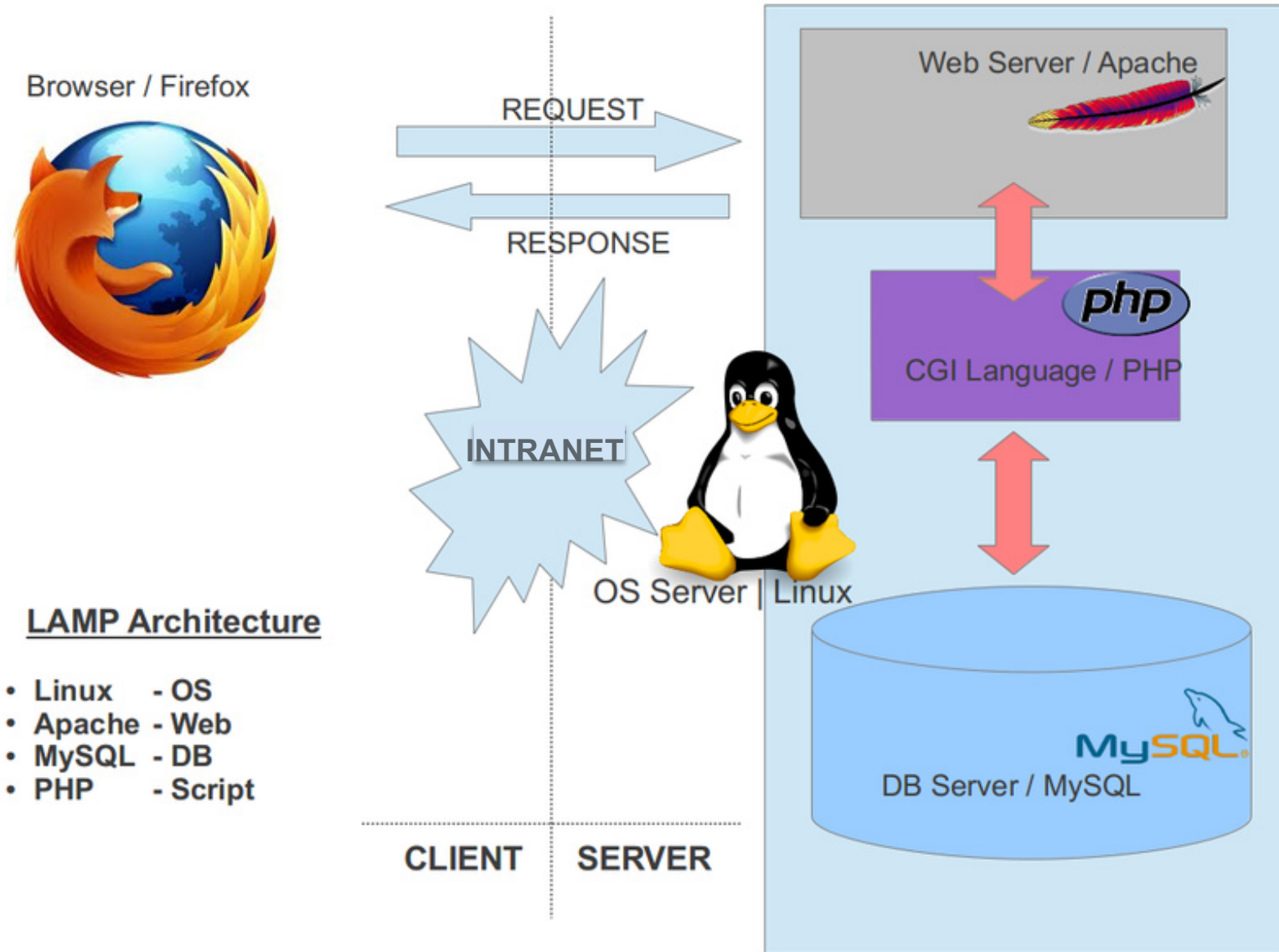
12 Applications

2 Validated

200+ Users

2 Developers

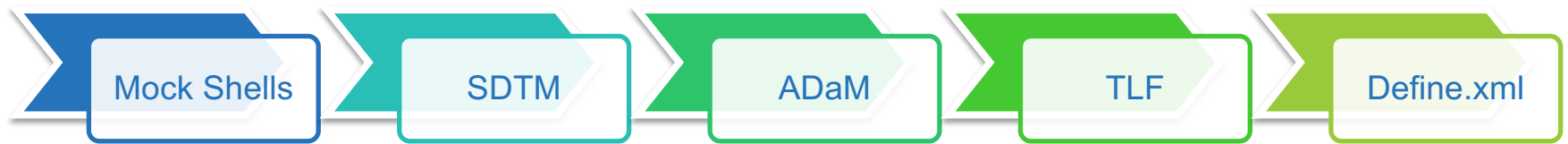
Web Application Architecture



Why Web?

- Open source, no licensing:
 - Written in PHP, JavaScript, Python, and MySQL, which are available for use with no licensing fees and are backed by large user communities.
- Rapid development:
 - Many existing modules/procedures which have undergone rigorous QA
 - Packages to automate common tasks are available and can be applied with little configuration (e.g.. PDF generation).
- Accessibility, Easy Deployment:
 - No separate software installation besides a web browser
 - Global updates are applied on the server side and no reinstallation is required.

Challenges in the Statistical Programming Process



Decentralized Information

High Project Management Time

Tedious Tasks

Biogen Web Applications

Workflow

- Tracks requests through their work cycle (Programmer to QC to Stats to Med. Writing)

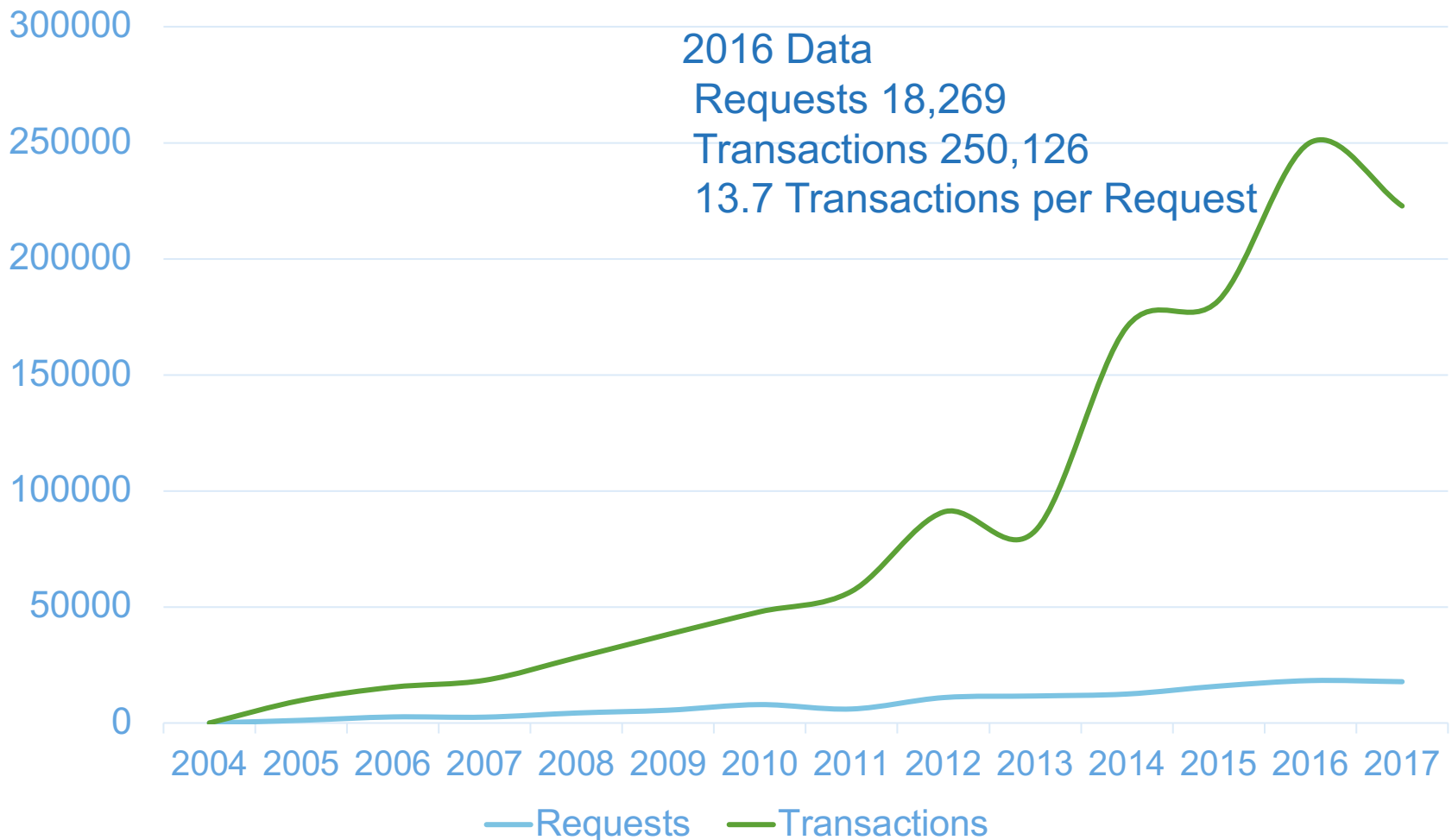
Phoenix

- Interface to enter SDTM/ADaM Dataset specifications
- Define.xml creation

Venus

- Interface to enter Mock TLF Shells

Project Management in Statistical Programming



Workflow


Workflow - drug/study/csr

Search  drug/study/csr

Workflow Getdata Setlist Phoenix Resources User Manuals

 Need Help?
 What's New
 Logout (pkumar)

Time: Year
Filters

Export ProgToc | Batch Processing

Requests by Project (drug/study/csr): 54 requests found
Sort by Table No

☐	Exploratory Analysis	Daniel Boisvert to Daniel Boisvert	drug/study/csr post-dbl	01/30/18 09:30	Unplanned	exploratory.sas qc-exploratory.sas	Table CR#105800
☐	New Tag				Development	f-histogram-r.sas QC not tracked in WF	Graphs CR#92246
☐					Planned	f-lb-byvis.sas qc-f-lb-byvis.sas	Graphs CR#101453
☐					Development	f-lb-heptox-bysubj.sas qc-f-lb-heptox-bysubj.sas	Graphs CR#101466
☐					Planned	f-lb-heptox.sas qc-f-lb-heptox.sas	Graphs CR#101465
☐					Planned	l-ae-ser.sas QC not tracked in WF	Listing CR#101280
☐					Planned	l-ae-wdw-drug.sas qc-l-ae-wdw-drug.sas	Listing CR#101459

Total Requests Selected: 1

Send/Run Selected (by Admin):

[Send to Primary Programmer for Revision](#)
[Send to QC Programmer](#)
[Send to Statistician 2](#)
[Re-assign to another Statistician 1](#)
[Mark as Retired](#)

[Run Primary programs in Selected Requests](#)
[Run QC programs in Selected Requests](#)

Other Actions:

[Copy](#)
[Assign Tags](#)
[Assign SAP Sections](#)
[Edit Role Fields](#)
[View Dependencies](#)

Workflow - Project Management

Workflow data is
analyzable and
reportable

Object	Status	Pgm Count	Output Count	% by Object
Analysis Dataset	Development	1	1	5
Analysis Dataset	Passed Stats	19	19	95
Table	Planned	1	1	0.4
Table	Development	11	11	4.3
Table	Released to MW	243	268	95.3
Listing	Development	4	4	15.4
Listing	Review-Stats	1	1	3.8
Listing	Released to MW	21	21	80.8
Figure	Development	3	3	50
Figure	Released to MW	3	28	50
Dataset	Review-QC	1	1	4
Dataset	Passed Stats	24	24	96
Other	Development	1	1	50
Other	Review-Stats	1	1	50
Total	Planned	1	1	0.3
Total	Unplanned	0	0	0
Total	Development	20	20	6
Total	Revise	0	0	0
Total	Review-QC	1	1	0.3
Total	Review-Stats	2	2	0.6
Total	Passed Stats	43	43	12.9
Total	Released to MW	267	317	79.9
Total		334	384	

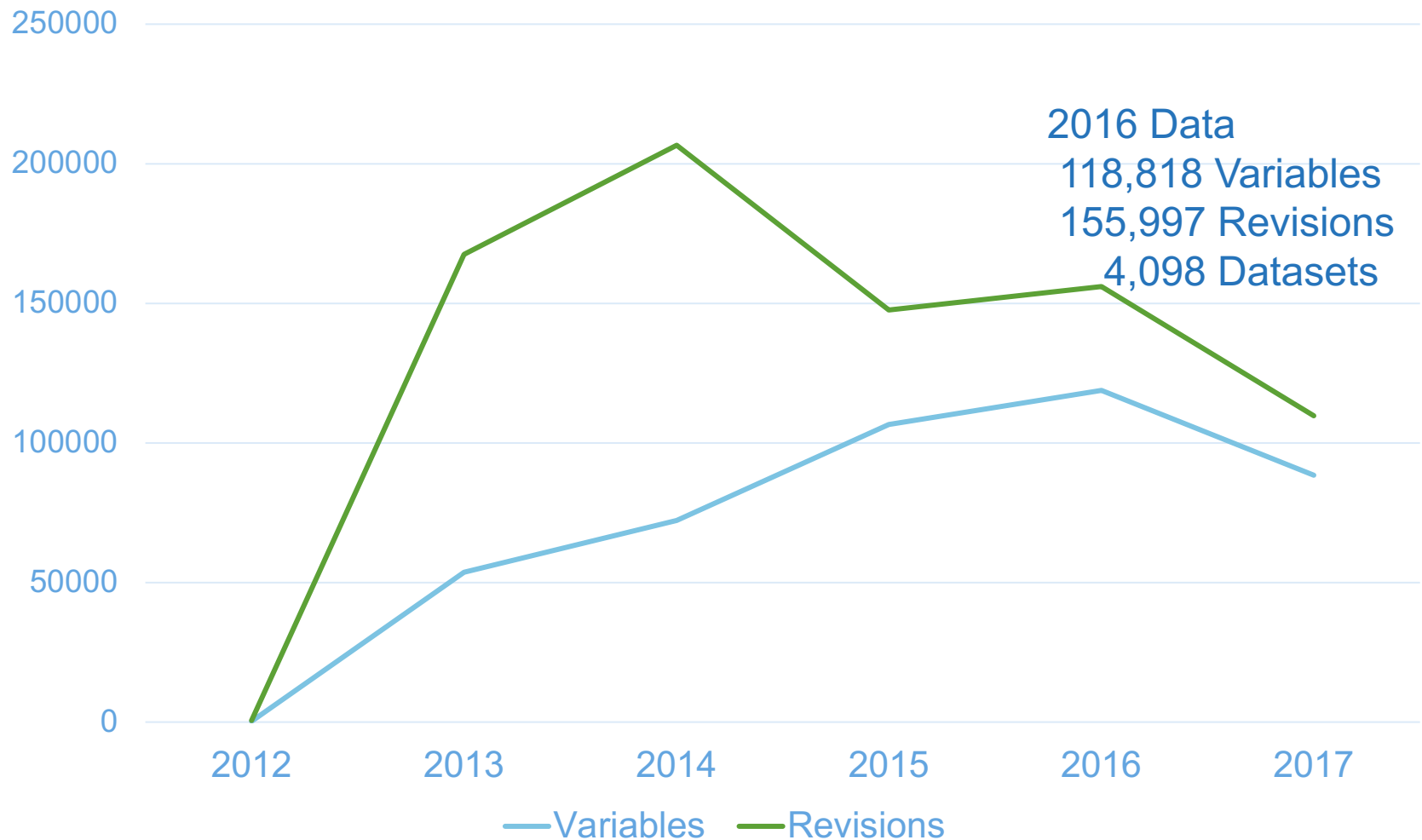
Workflow - Quantity, Quality, Duration Metrics

Quantity metrics	
Datasets (SDTM, ADAM, other ADs)	29
Programs	84
Outputs generated (1 program can generate multiple outputs)	90
Average outputs per program	1.07

Quality of work metrics	
% of TLGs revised post release to Medical Writing	0
Average transactions per SAS program	10.02
Summary metrics of reason for transactions	Data update 58(59%)
	Mismatch 22(22%)
	Spec change 19(19%)

Duration metrics	
Mean time to draft program (time from development to review)	Median: 10 Average: 17.72
Mean time to QC prior to stat review (time from review to review by stats)	Median: 11 Average: 18.29
Mean time to draft & QC prior to stat review (time from development to review by stats)	Median: 18 Average: 30.5
Mean time to complete stat review (time from review by stats to stable)	Median: 46 Average: 49.06
Mean time from draft to complete stat review (time from development to stable)	Median: 67 Average: 80.88

Decentralized Information – Dataset Specifications



Phoenix – Electronic Dataset Specifications


[Study](#)
[Insert/Edit Data](#)
[Other Resources](#)
[Logout dboisver](#)

Edit Dataset/Variable Level Metadata

Dataset ADSL ▼

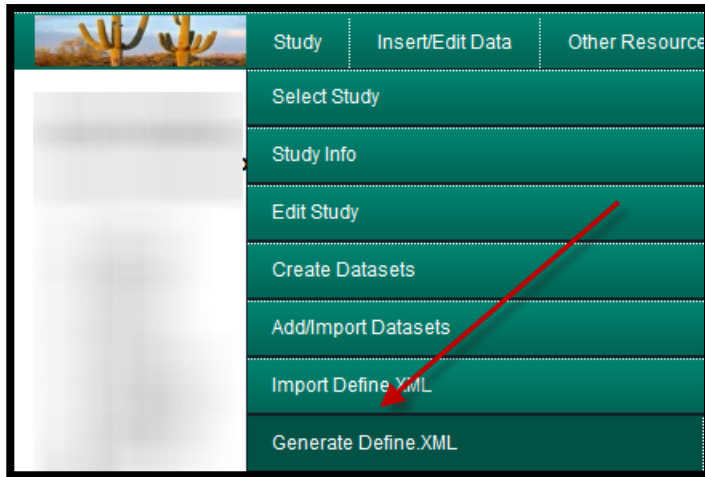
Dataset Options

Label: Subject Level Analysis Dataset **Purpose:** Analysis **Class:** SUBJECT LEVEL ANALYSIS
Structure: One record per subject
Keys: STUDYID, USUBJID
Notes:

Variable Level Metadata

Variable	Label	Comments (for define.xml)	Mapping Spec (Comment for Programmer)	Computational Method	Code List	Length	Type	Sig Digits	Origin
STUDYID	Study Identifier	DM.STUDYID	DO NOT REDERIVE; TAKE FROM DM			8	text	0	Derived
USUBJID	Unique Subject Identifier	DM.USUBJID	DO NOT REDERIVE; TAKE FROM DM			16	text	0	Derived
SUBJID	Subject Identifier for the Study	DM.SUBJID	DO NOT REDERIVE; TAKE FROM DM			7	text	0	Derived
SITEID	Study Site Identifier	DM.SITEID	DO NOT REDERIVE; TAKE FROM DM			3	text	0	Derived
COUNTRY	Country	DM.COUNTRY	DO NOT REDERIVE; TAKE FROM DM		COUNTRY	3	text	0	Derived
COUNTRYL	Country Full Name	This is the decode for COUNTRY to facilitate the presentation of country names in report USA=United States			[Create / Edit]	40	text	0	Assigned, Derived
BRTHDTC	Date/Time of Birth	DM.BRTHDTC	DO NOT REDERIVE; TAKE FROM DM			4	text	0	Derived

Phoenix – Write Data Once Use Multiple Times



```
*****
Creates global macro variables that contain all SAS dataset metadata contained
within Phoenix spec - this macro call should be at the beginning of the program
*****;
```

```
%create_attrib(dataset = adae );
```

```
*****
Outputs dataset to ../data/crt and XPT file (via %makexpt) to ../data/xpt
This macro call should be at the end of the program
*****;
```

```
%write_dataset(dataset=adae, dsout=adae);
```

Phoenix – Enforce Standards

Granular editing control

Import Variables from SDTM

Select Variables for EX Dataset

☐ DOMAIN ☒ EXENDY ☐ EXS

☐ EP1
☐ EXA
☐ EXC
☐ EXC
☐ EXC
☐ EXI
☐ EXI
☒ EXI
☒ EXI

This variable is required

OK

Edit Dataset

Dataset:

Label:**

Purpose:**

Edit Variable: USUBJID

Name **

Label **

Type **

Length **

Sig Digits:

Origin **

CRF Page No

Role

Core

SAS Format Name:

Tedious Tasks - Mock Table Shell

Creation

Table 3: Demography - <population >

Page 1 of 2

	Placebo (N=xxx)	Active drug 1 (N=xxx)	Active drug 2 (N=xxx)
Number of subjects	nnn	nnn	nnn
Age categories (years)	nn (100)	nn (100)	nn (100)
<xx	nn (pp.p)	nn (pp.p)	nn (pp.p)
xx to xx	nn (pp.p)	nn (pp.p)	nn (pp.p)
xx to xx	nn (pp.p)	nn (pp.p)	nn (pp.p)
>xx	nn (pp.p)	nn (pp.p)	nn (pp.p)
Age (years)			
n	nn	nn	nn
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx	xx	xx
Q1,Q3	xx,xx	xx,xx	xx,xx
Min, Max	xx,xx	xx,xx	xx,xx
Sex	nn (100)	nn (100)	nn (100)
Male	nn (pp.p)	nn (pp.p)	nn (pp.p)
Female	nn (pp.p)	nn (pp.p)	nn (pp.p)
Ethnicity	nn (100)	nn (100)	nn (100)
Hispanic or Latino	nn (pp.p)	nn (pp.p)	nn (pp.p)
Not Hispanic or Latino	nn (pp.p)	nn (pp.p)	nn (pp.p)

Source: drug/study/csr/t-progname.sas:outputname.rtf| Data as of: DDMONYY| Run date: DDMONYY

Venus – Paper to Data, Targeted Functionality

 **eMock Shells** Selected study: drug/study/accruals

Study Settings Workflow Export to Pdf file User Guide [Need help?](#) | [Logout](#)

Select Study:

[STAN](#) | [Copy from another study](#) | [Add new](#)

Table xx: Title goes here

Select		Treatment 1 (N=xxx)	Treatment 2 (N=xxx)	Treatment 3 (N=xxx)	
☐					+ +
☐	Age				+ +
☐	n				+ +
☐	Mean (SD)				+ +
☐	Median				+ +
☐	Min, Max				+ +
☐					+ +

Footnotes:

Source: drug/study/accruals/t-programname.sas/outputname.rtf| Data as of: DDMMYY| Run date: DDMMYY

Programming Notes:

Program name:

Add new Column

Treatment labels automatically entered from centrally stored data.

Indent text

Venus – Enforce Table Standards

**eMock Shells** Selected study: drug/study/accruals

**eMock Shells** Selected study: drug/study/accruals

Study SettingsWorkflowExport to Pdf fileUser Guide

Select Study:

[STAN](#) | [Copy from another study](#) | [Add new](#)
[: Table xx: Title goes here](#)

Demographics
☐ 1: Demography - <population >

Adverse Events
☐ 2: Overall summary of adverse events - safety population
☒ 3: Adverse events by system organ class and preferred term sorted by decreasing frequency - safety population
☐ 4: Adverse events by system organ class and preferred term sorted by alphabetical order - safety population
☐ 5: Adverse events by system organ class - safety population
☐ 6: Adverse events at least x% higher in incidence by system organ class and preferred term for <active> compared to <placebo> - safety population
☐ 7: Adverse events by preferred term - safety population
☐ 8: Adverse events by preferred term with an incidence of x% or more safety population
☐ 9: Severe adverse events by system organ class and preferred term - safety population
☐ 10: Severe adverse events by preferred term - safety population
☐ 11: Adverse events by maximum severity by system organ class and preferred term - safety population
☐ 12: Adverse events by maximum severity by preferred term - safety population
☐ 13: Related adverse events by system organ class and preferred term - safety population
☐ 14: Serious adverse events by system organ class and preferred term - safety population
☐ 15: Serious adverse events by preferred term - safety population
☐ 16: Listing of serious adverse events - safety population

Save to drug/study/accruals **Close and refresh main window**

Select Phase: - no selection - ▼

Demographics
☒ Demography - <population >

Adverse Events
☒ Overall summary of adverse events - safety population
☒ Adverse events by system organ class and preferred term sorted by decreasing frequency - safety population
☒ Adverse events by system organ class and preferred term sorted by alphabetical order - safety population
☒ Adverse events by system organ class - safety population
☒ Adverse events at least x% higher in incidence by system organ class and preferred term for <active> compared to <placebo> - safety population
☒ Adverse events by preferred term - safety population
☒ Adverse events by preferred term with an incidence of x% or more safety population
☒ Severe adverse events by system organ class and preferred term - safety population
☒ Severe adverse events by preferred term - safety population
☒ Adverse events by maximum severity by system organ class and preferred term - safety population
☒ Adverse events by maximum severity by preferred term - safety population
☒ Related adverse events by system organ class and preferred term - safety population
☒ Serious adverse events by system organ class and preferred term - safety population
☒ Serious adverse events by preferred term - safety population
☒ Listing of serious adverse events - safety population
☒ Related serious adverse events by system organ class and preferred term - safety population
☒ Adverse events that led to discontinuation of study drug by system organ class and preferred term - safety population
☒ Listing of adverse events that led to discontinuation of study drug safety population
☒ Adverse events that led to withdrawal from study by system organ class and preferred term - safety population
☒ Listing of adverse events that led to withdrawal from study - safety population
☒ Adverse events that led to <drug interrupted, dose reduced, dose increased value to match CRF> - safety population
☒ Incidence rates of adverse events by system organ class and preferred term - safety population

Laboratory Analyses
☒ Hematology actual values by visit - safety population
☒ Hematology <mean/median> values by visit - safety population
☒ Hematology change from baseline by visit - safety population

Source: drug/study/accruals/t-progname.sas:outputname.rtf | Data as of: DDMONVY | Run date: DDMONVY

Programming Notes:



Copy all standard tables in one click.



Future

- Predictive Analytics
 - Predict Request Assignment
 - Predict Total Work
- Automation
 - Tie systems together to reduce manual intervention
- Innovation
 - Venus to create tables/listings using only PHP, Python

Conclusion

- High level overview of key functionality
- Web development presents a opportunity to improve statistical programming processes with low overhead

Questions

